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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,159

02/13/2006

Giuseppe Caputo

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EXAMINER

CHU, YONG LIANG

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

05/29/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,159	Applicant(s) CAPUTO, GIUSEPPE	
	Examiner YONG CHU	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,8,9 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) 6,8,9 and 14-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4 is/are rejected.
- 7) ☒ Claim(s) 1,2, and 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/10/2009 has been entered. Upon entering the submission, claims 1-2, 4, 6, 8-9, 14-16 pending in the instant application. Claims 6, 8-9, and 14-16 remain withdrawn as non-elected subject matter. Claims 1-2 and 4 are under examination on the merits.

Response to RCE Submission

Foreign Priority Claim

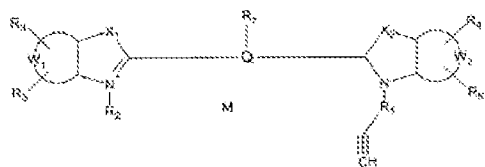
Applicants' amendment of the specification to list the foreign priority claim to PZ2003000002 in the first sentence of the specification obviates the objection.

Claim rejection under 35 U.S.C. §103(a)

Applicants' have amended the rejected claims 1-2 and 4. The rejection is moot. Upon further search and examination, the amended claims 1-2 and 4 are rejected under 35 U.S.C. §103(a) as being unpatentable over Takashima et al. (US2002/0051926 or the "926 application") in view of Caputo et al. (US2002/065421 or the "421 application"), Stavrianopoulos et al. (US2003/0225247 or the "247 application"), and Greg T. Hermanson, *Bioconjugate Techniques*, (1996), P.228-229, and 287 (the "Hermanson") and the incorporated references.

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The currently examined claims 1-2 and 4 are drawn to a compound of the

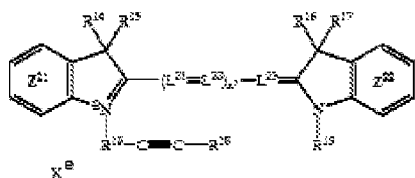


Formula I

according to claim 1, wherein: **R₁** is an

alkyl chain; **X₁** and **X₂** are both $-\text{C}(\text{CH}_3)_2$, and **W₁** and **W₂** are both benzene ring or a naphthalene ring without heteroatom substitution.

The '926 application disclosed a cyanine-based organic dye of formula (3)



according to claim 20, wherein **R¹³**, **R¹⁴**, **R¹⁵**, **R¹⁶**, **R¹⁷** and

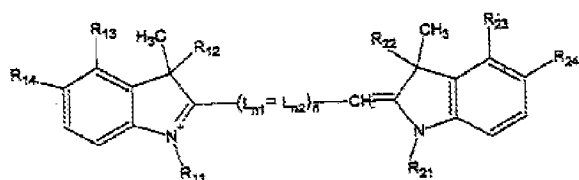
R¹⁸ each represents a hydrogen atom, an aliphatic group, or an aromatic group; **R¹⁹** represents a bivalent aliphatic group; **L²¹**, **L²²**, and **L²³** each independently represents a methine group that may have a substituent, and, if **L²¹**, **L²²**, and **L²³** each represents a methine group that has a substituent, the substituents may join together to form an unsaturated aliphatic ring or an unsaturated heterocycle; **Z²¹** and **Z²²** are benzene rings, with which other benzene rings may be condensed, and the benzene rings **Z²¹** and **Z²²** and benzene rings condensed therewith may each have a substituent; **n** represents 0, 1, 2, or 3; and **X⁻** represents a group capable of forming an anion.

At paragraph [0048] of the specification, an aliphatic group is exemplified as an optionally substituted alkyl group, optionally substituted alkenyl group, optionally substituted aralkyl group,...and an optionally substituted alkyl group are particularly

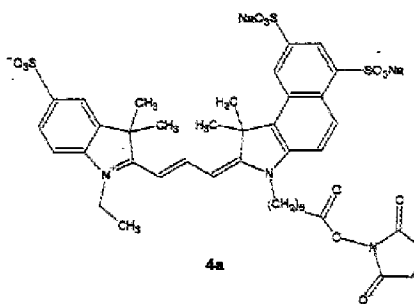
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preferable. At the paragraph [0052], the substituent of the substituted alkyl group is further exemplified as a carboxyl group, a sulfo group, a cyano group, a hydroxyl group, a sulfo group, nitro group, etc.

The '421 application disclosed a class of indocyanine compound

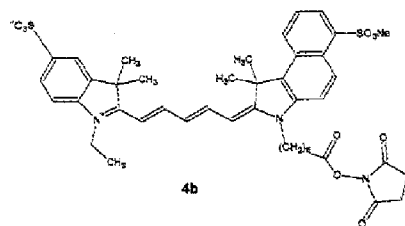


in Fig. 1, used as a biomolecular labeling



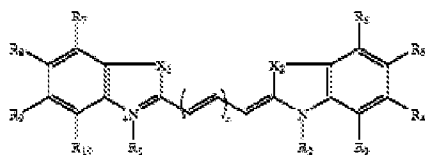
reagent with specific examples

and



in Fig 7.

The '247 application disclosed a cyanine-based organic dye of formula



, wherein **X₁**, and **X₂** are carbon, and **R₁**, through

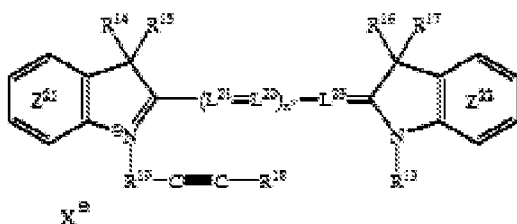
R₁₀ are reacting group capable of forming a carbon-carbon linkage with a biological

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target, and n is 1, 2, or 3. These compounds are used as dye probe for labeling biomolecules such as DNA, RNA, protein, or peptide as disclosed in abstract.

Hermanson teaches commonly used biocunjugate techniques on how to label a biological molecule (e.g. DNA, RNA, peptides, carbohydrates) with a mono-, bi-, and multiple-function linkers, activating groups, as well as the application of the biocunjugates. The bi- and/or multiple-function linkers have different activity toward targeting biological molecules, and function discriminately toward different targets.

The difference between the '926 application and the instantly claimed invention, is that the '926 application teach an alkynyl-linker indocyanine dye



with a substituent R^{13} as H, an optionally

substituted aliphatic group, or an optionally substituted aromatic group bonding to the indole ring (i.e. W_1 -indole ring), but does not teach specifically a compound with R^{13} as $-COOH$, $-OH$, $-NO_2$, $-OCH_3$, $-SO_3H$, or $-SO_3$ as claimed as R_2 in the instant claim 1.

However, the '926 application does teach that R^{13} is a substituted alkyl, wherein the substituents are carboxyl group, a cyano group, a hydroxyl group, amino group, a heterocyclic group, sulfo group, an aryl group, which reads on the instantly claimed scope of the compounds, wherein R_2 is $-R_8-Y$, wherein R_8 is an alkyl chain, and Y is carboxyl, amino, sulfhydryl, hydroxyl, etc. In addition, the '421 application teaches indocyanine compounds are used to label a biological molecule through a linker to the

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indocyanine compounds. The '247 application discloses a cyanine-based organic dye and a method of labeling DNA, RNA, protein, or peptide through the substituents of R_1 through R_{10} as reacting group capable of forming a carbon-carbon linkage with the biological molecules. The various biological linkers for making biological conjugates through mono-, bi-, and multiple-function linkers are taught the Hermanson reference. The variable linkers for the instant application are at the grasp of one skilled in the art with the combining prior art teachings from the '247 application and the Hermanson reference. The instantly claimed invention would be *prima facie* obvious over the teaching of **the combined prior art teachings** as a whole.

Obviousness-type Double Patenting rejection

Applicants' argument over ODP rejection on the ground that the '612 patent does not contain an alkynyl-linker of indocyanine, and has the same and identical linkers has been fully considered, and found persuasive. Therefore, the rejection has been withdrawn.

Claim Objections

Claims 1-2 and 4 remains provisionally objected for containing non-elected subject matter. The elected subject matter has been identified supra. The elected subject matter will be addressed following a determination of allowable subject matter.

Claim 1 is objected to because of the following informalities: at lines 14-15, page 1 of claim 1, “-CH=CH-, wherein R_2 ” and “- R_8 -Y, wherein R_3 ” is not an appropriate

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Markush-type claim. It should be “-CH=CH-; R₂” and “-R₈-Y; R₃”. Appropriate correction is required.

Conclusion

No claim is allowed.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu, Ph.D, whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Yong Chu/
Patent Examiner
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